UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,840	12/01/2000	Johnatan Bacon	9463-014-999	4238

20583 7590 02/26/2003

PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 100362711

EXAMINER
JOYNES, ROBERT M

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 02/26/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/728,840	BACON ET AL.	
	Examiner	Art Unit	
	Robert M. Joynes	1615	

-- The MAILING DATE of this communication app ars on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-19* is/are pending in the application.

4a) Of the above claim(s) 2 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of applicants' Request for Continued Examination filed on December 10, 2002.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 3-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal in view of Rosenthal (US 2895880). Baichwal teaches a sustained release composition comprising an active agent and excipients (Page 2, lines 5-24). The excipient matrix may include one or more heteropolysaccharide, preferably xanthan gum (Page 4, lines27-35), a cross-linking agent (Page 5, line 19 – Page 6, line 3), hydrophobic material such as zein (Page 7, lines 18-32) and an active agent. The hydrophobic material may be present in the composition in amounts from about 1% to about 20% by weight of the final formulation (Page 8, lines 1-10). The active agent may be an antihistamine, analgesic, anti-inflammatory agent, anti-epileptic agent, anti-emetics agent, vasodilator, anti-tussive agent, anti-asthmatic agent, anti-spasmodic, hormone, diurectic, anti-hypotensive agent, antibiotic and others (Page 12, line 17 – Page 13, line7). The composition may further contain an inert pharmaceutical diluent such as a starch (Page 17, Claim 1). Finally, the amount of hydrophobic material (zein)

determines how quickly or slowly the gums hydrate upon exposure to environmental fluid (Col. 6, lines 26-30).

Baichwal does not expressly teach the exact range of gelling agents and prolamins recited in instant Claim 1. The reference also does not teach every active agent or gelling agent or prolamin recited in the instant claims.

Rosenthal teaches a sustained release formulation in which the amount of prolamin is from 20% to 45% by weight of the total composition (Col. 1, lines 33-46).

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a sustained-release formulation with an excipient matrix comprising a prolamin, one or more gelling agents, one or more additional excipients and an active agent. It is within the skill of the art to vary the ingredient (the prolamin, gelling agents, active agents and additional excipients) to achieve the same expected result. Baichwal teaches that the amount of hydrophobic material (zein) controls the rate at which the gums hydrate therefore causing the sustained release effect. It would be obvious to one or ordinary skill to vary the rate of sustained release

and it would be obvious to do so by varying the amount hydrophobic material in the composition.

One of ordinary skill in the art would have been motivated to do this to produce a composition that releases the active agent over an extended period of time.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1 and 3-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal in view of Baichwal. The teachings of Rosenthal and Baichwal are discussed above.

Briefly, Rosenthal teaches a sustained release composition in which prolamins are present from about 20% to about 45% of the total weight of the composition. Rosenthal does not expressly teach the inclusion of gelling agents.

Baichwal teaches a sustained release formulation in which the sustained release composition comprises an active agent and an excipient matrix (Page 2, lines 5-24). The excipient matrix may include one or more heteropolysaccharide, preferably xanthan gum (Page 4, lines27-35), a cross-linking agent (Page 5, line 19 – Page 6, line 3), hydrophobic material such as zein (Page 7, lines 18-32) and an active agent.

Neither reference teaches the complete concentration ranges recited in the instant claims.

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or

temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a sustained-release formulation with an excipient matrix comprising a prolamin, one or more gelling agents, one or more additional excipients and an active agent. It is within the skill of the art to vary the ingredient (the prolamin, gelling agents, active agents and additional excipients) to achieve the same expected result. It would be obvious to add a gelling agent to the prolamins of Rosenthal to prepare a sustained release matrix.

One of ordinary skill in the art would have been motivated to do this to produce a composition that releases the active agent over an extended period of time. One would be motivated to add the gelling agent to the prolamins composition of Rosenthal to provide a sustained release composition that forms a gel upon exposure to the environment fluid that causes a better sustained release of the active medicament in the gastrointestinal tract wherein the gel forms, is more rigid and prevent an initial burst of drug when exposed to the environment fluids.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703)

308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
February 24, 2003

Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600